

JUN 29 2011

## 510K SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Devices Act of 1990 and 21 CFR 807.92

The assigned 510(k) number is: K110616

### Company/Contact person

Lisa Charter  
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Microgenics Corporation  
Thermo Fisher Scientific, Clinical Diagnostics Division  
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### Date Prepared

June 20, 2011

### Regulatory Declarations

Common / Usual Name	MAS <sup>®</sup> Omni•IMMUNE MAS <sup>®</sup> Omni•IMMUNE PRO
Trade/ Proprietary Name	Thermo Scientific MAS <sup>®</sup> Omni•IMMUNE Thermo Scientific MAS <sup>®</sup> Omni•IMMUNE PRO
Classification Regulation	21 CFR 862.1660
Device Class	Class I
Device Regulation Panel	Clinical Chemistry
Product Code	JJY

### Intended use

Thermo Scientific MAS<sup>®</sup> Omni•IMMUNE is intended for use as an assayed control for monitoring assay conditions in many clinical laboratory determinations. Include Omni•IMMUNE with patient serum specimens when assaying for any of the listed constituents. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument

Thermo Scientific MAS<sup>®</sup> Omni•IMMUNE PRO is intended for use as an assayed control for monitoring assay conditions in many clinical laboratory determinations. Include Omni•IMMUNE PRO with patient serum specimens when assaying for any of the listed constituents. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.

### Legally marketed device to which equivalency is claimed

Thermo Scientific MAS Omni•IMMUNE Control is substantially equivalent to the previously cleared Bio-Rad Laboratories Lyphocheck Immunoassay Plus Control (K981532).

#### **Description of Device**

Omni•IMMUNE is a liquid stable control material prepared from human serum. Analyte levels are adjusted with various pure chemicals and preparations from human tissue or body fluids. Preservatives and stabilizers are added to maintain product integrity.

The control is offered in three levels with the following configuration:

<b>MAS® Omni•IMMUNE</b>		
<b>Catalog Number</b>	<b>Description</b>	<b>Size</b>
OIM-101	Level 1	6 vials of Level 1, 5 mLs per vial
OIM-202	Level 2	6 vials of Level 2, 5 mLs per vial
OIM-303	Level 3	6 vials of Level 3, 5 mLs per vial
OIM-SP	Sample-pack	1 vial of Level 1, 5 mLs per vial 1 vial of Level 2, 5 mLs per vial 1 vial of Level 3, 5 mLs per vial
<b>MAS® Omni•IMMUNE PRO</b>		
<b>Catalog Number</b>	<b>Description</b>	<b>Size</b>
OPRO-1	Level 1	6 vials of Level 1, 5 mLs per vial
OPRO-2	Level 2	6 vials of Level 2, 5 mLs per vial
OPRO-3	Level 3	6 vials of Level 3, 5 mLs per vial
OPRO-SP	Sample-pack	1 vial of Level 1, 5 mLs per vial 1 vial of Level 2, 5 mLs per vial 1 vial of Level 3, 5 mLs per vial

## Comparison of Technological Characteristics

Comparison	Subject Device	Predicate
<b>Device</b>	MAS <sup>®</sup> Omni•IMMUNE MAS <sup>®</sup> Omni•IMMUNE PRO	Bio-Rad Lyphochek <sup>®</sup> Immunoassay Plus Control
<b>510(k) number</b>	K110616	K981532
<b>Intended Use</b>	<p>Thermo Scientific MAS<sup>®</sup> Omni•IMMUNE is intended for use as an assayed control for monitoring assay conditions in many clinical laboratory determinations. Include Omni•IMMUNE with patient serum specimens when assaying for any of the listed constituents. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument</p> <p>Thermo Scientific MAS<sup>®</sup> Omni•IMMUNE PRO is intended for use as an assayed control for monitoring assay conditions in many clinical laboratory determinations. Include Omni•IMMUNE PRO with patient serum specimens when assaying for any of the listed constituents. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.</p>	Lyphochek Immunoassay Plus Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
<b>Matrix</b>	Human Serum	Human Serum
<b>Form</b>	Frozen Liquid	Lyophilized
<b>Control Levels</b>	Level 1 Level 2 Level 3	Level 1 Level 2 Level 3
<b>Storage</b>	-20°C	2-8°C
<b>Open Vial Stability</b>	30 days (2-8 °C)	7 days (2-8 °C) except <ol style="list-style-type: none"> <li>1. C-Peptide, Folate and PSA (stable for 3 days after reconstitution).</li> <li>2. ACTH, Calcitonin and Gastrin (Should be assayed immediately after reconstitution).</li> </ol>
<b>Shelf Life</b>	36 months	36 months
<b>Analytes by Configuration</b>	17-alpha-OH Progesterone 25-Hydroxy Vit D Acetaminophen ACTH AFP	17-alpha-OH Progesterone 25-Hydroxy Vit D Acetaminophen ACTH AFP

Aldosterone	Aldosterone
Amikacin	Amikacin
Anti-Tg (PRO Version Only)	Anti-Tg
Anti-TPO (PRO Version Only)	Anti-TPO
Benzodiazepine	-
Beta-2-Microglobulin	-
CA 125	-
CA 15-3	-
CA 19-9	-
β-hCG	Calcitonin
Carbamazepine	β-hCG
CEA	Carbamazepine
CK-MB (MMB)	CEA
Cortisol	-
C-Peptide	Cortisol
DHEA-Sulfate	C-Peptide
Digoxin	DHEA-Sulfate
Disopyramide	Digoxin
Estradiol	Disopyramide
Estriol free	Estradiol
Ethosuximide	Estriol free
Ferritin	Ethosuximide
Folate	Ferritin
Fructosamine	Folate
FSH	Fructosamine
Gastrin	FSH
Gentamicin	Gastrin
Growth Hormone	Gentamicin
hCG	Growth Hormone
Homocysteine	hCG
IgE	-
IGF-1	IgE
Inhibin A	-
Insulin	-
LH	Insulin
Lidocaine	LH
Lithium	Lidocaine
NAPA	Lithium
PAP	NAPA
Phenobarbital	-
Phenytoin	PAP
Phenytoin, Free	-
Primidone	Phenobarbital
Procainamide	Phenytoin
Procalcitonin	Phenytoin, Free
Progesterone	Primidone
Prolactin	Procainamide
PSA	-
Free PSA	Progesterone
PTH, Intact	Prolactin
Quinidine	PSA
Salicylate	Free PSA
SHBG (PRO Version Only)	PTH, Intact
TBG	Quinidine
T3	Salicylate
Free T3	SHBG

	T4 Free T4 Testosterone Theophylline Thyroglobulin Tobramycin Tri-Cyclic Antidepressants TSH T-Uptake Valproic Acid Valproic Acid, Free Vancomycin Vitamin B12	TBG T3 Free T3 T4 Free T4 Testosterone Theophylline Thyroglobulin Tobramycin Tri-Cyclic Antidepressants TSH T-Uptake Valproic Acid Valproic Acid, Free Vancomycin Vitamin B12
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### Conclusion

As summarized, the Omni•IMMUNE Control is substantially equivalent to the previously cleared Bio-Rad Lyphochek® Immunoassay Plus Control (K981532). Substantial equivalence has been demonstrated through performance testing to verify that the device functions as intended and that design specifications have been satisfied.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Microgenics Corporation  
Thermo Fisher Scientific Clinical Diagnostic Division  
c/o Ms. Lisa Charter  
Manager, Regulatory Affairs  
46360 Fremont Blvd.  
Fremont, CA 94538

Food & Drug Administration  
10903 New Hampshire Avenue  
Building 66  
Silver Spring, MD 20993

**JUN 29 2011**

Re: k110616  
Trade Name: Thermo Scientific MAS Omni-Immune, Thermo Scientific MAS  
Omni-Immune Pro  
Regulation Number: 21 CFR §862.1660  
Regulation Name: Quality Control Material (assayed and unassayed)  
Regulatory Class: Class I, reserved  
Product Codes: JJY  
Dated: May 19, 2011  
Received: May 23, 2011

Dear Ms. Charter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

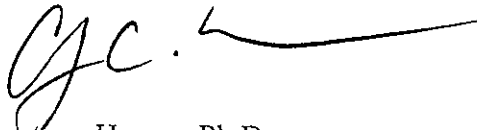
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'CH' with a long horizontal stroke extending to the right.

Courtney Harper, Ph.D.  
Director  
Division of Chemistry and Toxicology  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indication for Use

510(k) Number (if known): K110616

Device Name: Thermo Scientific MAS® Omni•IMMUNE  
Thermo Scientific MAS® Omni•IMMUNE PRO

### Indication for Use:

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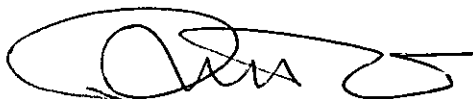
Prescription Use   X    
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use         
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k)   K110616